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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,221	11/20/2003	Kim Seah Goh	303798 46623	9025

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

8

Office Action Summary	Application No. 10/718,221	Applicant(s) GOH, KIM SEAH	
	Examiner Christopher D. Koharski	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-12,15-22 and 25-30 is/are rejected.
- 7) ☒ Claim(s) 3,4,13,14,23 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/20/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 2/28/2007 in which claims 1, 11, 13 and 20 were amended. Currently claims 1-30 are pending for examination in this application.

Drawings

The informal drawings are not of sufficient quality to permit examination. Examiner asserts that key distinguishing features are NOT clearly visible in the low quality supplied drawings (specifically figures 3 and 4). Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

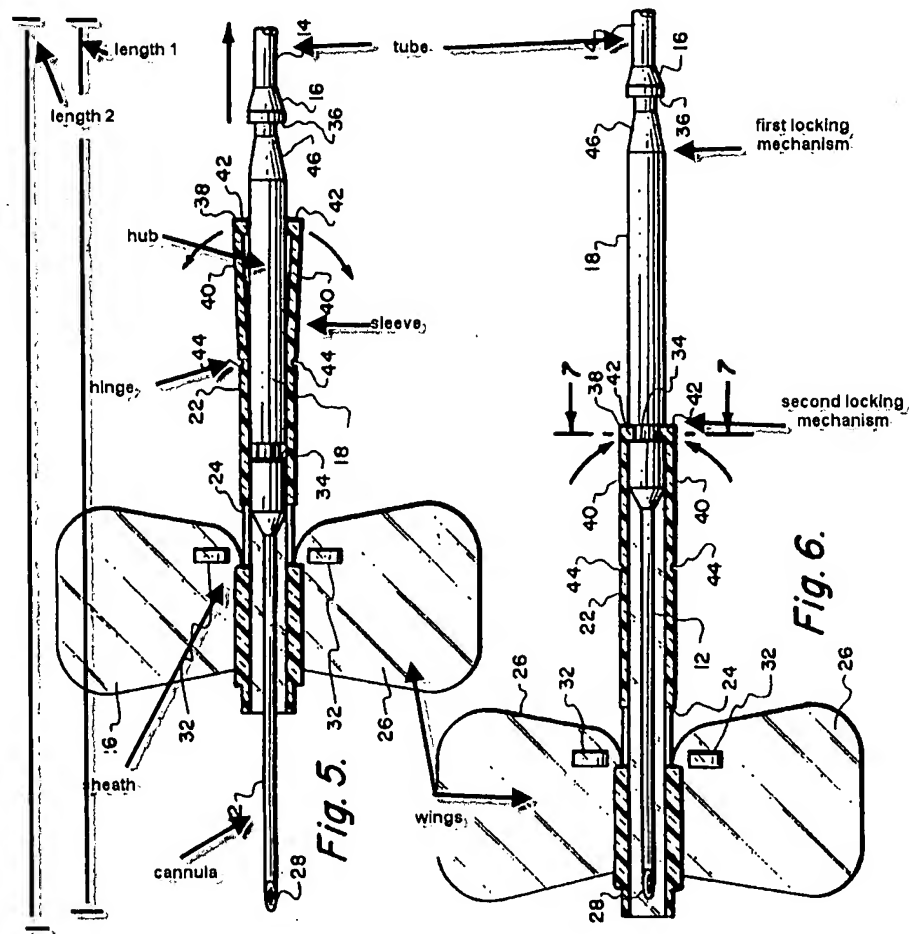
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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5, 10-12, 18-22, 25, 28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lam (5,382,240). Lam discloses a cannula guard.

Regarding claims 1-2, 5, 10-12, 18-22, 25, 28 and 30, Lam discloses a telescopic winged safety needle assembly, comprising a hub (20) having a distal end, a proximal end (Figure 4), and an axial hole therethrough, a rotatable cannula (12) joined to said hub adjacent the distal end of the hub, a cylindrical sleeve (element covering 18, closest to 40) having a locking tab (near 42) attached thereto by a hinge (44), said cylindrical sleeve being axially disposed on said hub (Figures 5-6), a cylindrical sheath (see marked up drawing below, near 24) for retaining said hub therein and having a distal end and a proximal end, said hub being slidable along an interior surface of said cylindrical sleeve and sheath (emphasis added) (see Figures 5-6) from a first telescopic position (Figure 5) at which the distal end of said cannula joined to said hub projects beyond the distal end of the cylindrical sheath by a predetermined length, to a second position which is maximized in length (Figure 6) at which the distal end on the cannula is protectively covered within said cylindrical sheath, with said cylindrical sleeve being axially disposed on said proximal end of said cylindrical sheath (see Figures 1-6 and marked up drawing below), a pair of flexible wings (26) provided on the outer peripheral surface adjacent the distal end of said cylindrical sheath, a first and second locking mechanism comprising tabs and grooves, (near 46, 34) disposed on said assembly whereby the first locking mechanism releasably locks said hub, said sleeve and said sheath at the first position and a second locking mechanism that unreleasably lock said

hub, sleeve and sheath at the second position, with a tube (14) being attached to the proximal end of the hub (see Figures 1-6 and marked up drawing below).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 15 and 26 are rejected under 35 U.S.C 103(a) as being unpatentable over Lam in view of Tal (US2003/0153874). Lam meets the claim limitations as described above except for the use of a marking to indicate the needle orientation.

However, Tal teaches a vascular access device.

Regarding claims 6, 15 and 26, Tal teaches the use of indicating marks of various markings (color coding, words, other marks), which indicate the needle bevel level and the needle position within the assembly ([0014]).

At the time of the invention, it would have been obvious to add the indicating markings of Tal to the systems of Lam because the addition of the indicating markings allows control and feedback to the user regarding needle position. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Tal.

Claim Rejections - 35 USC § 103

Claims 7, 16 and 27 are rejected under 35 U.S.C 103(a) as being unpatentable over Lam in view Maclean Crawford et al. (6,659,984). Lam meets the claim limitations

as described above except for the specific openings and locking tabs located in the outer cylindrical sheath.

However, Maclean Crawford et al. teaches a needle safety assembly.

Regarding claims 2, 7, 22 and 27, Maclean Crawford et al. teaches a needle assembly with an outer cylindrical sheath with two openings (68, 72) that provides a locking mechanism with locking tabs (70, 42) (Figures 1-3).

At the time of the invention, it would have been obvious to include the locking system of Maclean Crawford et al. to the systems of Lam because the addition of this external locking system allows the user to view the needle hub/sleeve position through the openings. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Maclean Crawford et al.

Additionally, Examiner asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the locking mechanism of Lam or Liu with the openings and locking tabs in the cylindrical sheath, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Claim Rejections - 35 USC § 103

Claims 9, 17 and 29 are rejected under 35 U.S.C 103(a) as being unpatentable over Lam in view of Dillon et al. (5,833,670). Lam meets the claim limitations as described above except for the ribs along an sleeve inner surface to guide the hub.

However, Dillon et al. teaches a protective needle device.

Regarding claims 9, 17 and 29, Dillion et al. teaches a needle assembly (4) with a sleeve (6) and a hub (12) in which several ribs (8, 16) are provided for controlled movement of the hub through the sleeve (Figures 1A-1C).

At the time of the invention, it would have been obvious to incorporate the ribs of Dillion et al. to the device of Lam for an additional safety measure to provide and prevent needle stick by allowing controlled retraction movement of the needle hub. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Dillon et al. (see summary of invention).

Allowable Subject Matter

Claims 3-4, 13-14 and 23-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Suggested Allowable Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests the addition of a specific claim limitation drawn the sheath and sleeve elements being separate and sliding over each other as seen in Figure 4.

Response to Arguments

Applicant's arguments filed 2/28/2007 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Lam reference does not show the elements of the hub, sleeve, and sheath with the hub being slidable along an inner surface of said sheath and an inner surface of said sleeve. In Applicant's arguments, Applicant Representative summarily dismissed the Examiners rejection by examining the patent reference terms and not Examiner's interpretation of the reference and the claims of the application at hand. Examiner has included a marked up drawing of the specific elements in question, and the interpretation thereof. As shown in the drawings and highlighted in the rejection above the reference clearly shows the elements argued in their respective positions as currently claimed by Applicant, of specific note the sleeve being axially disposed on said proximal end of said cylindrical sheath and the assembly being maximized in length at a second telescopic position as indicated in the marked up drawings by the different associated lengths.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: 5,928,199 and 5,746,215 (see PTO-892).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

5/8/07


Christopher D. Koharski
AU 3763

Primary Examiner